IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Art Unit: 1642
Dave S. B. Hoon et al.	Examiner: Sean E. Aeder
Serial No.: 10/713,808	
Confirmation No.: 4483	
Filed: November 14, 2003	
For: DETECTION OF MICROMETASTASIS OF MELANOMA AND BREAST CANCER IN PARAFFIN-EMBEDDED TUMOR DRAINING LYMPH NODES BY MULTIMARKER QUANTITATIVE RT-PCR	

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

1. I, Dave S.B. Hoon, of 1911 Malcolm Avenue, Los Angeles, CA 90025 declare as follows.

2. I am named as one of the two inventors for the U.S. Patent Application No. 10/713,808 filed on November 14, 2003 (hereinafter, referred to as "the application").

3. I am a Director of Department of Molecular Oncology and a Full Member at John Wayne Cancer Institute, 2200 Santa Monica Boulevard, Santa Monica, CA 90404, and have held this position since 1997. My qualifications and previous appointments are set out below:

Qualifications

B.S. in Functional Biology, Victoria, B.C. University, 1977.

Ph.D. in Immunology/Microbiology, Sasketchewan University, 1983.

Previous Appointments

Position, Institution	Dates
Director of Department of Molecular Oncology and Full Member, John Wayne Cancer Institute	1997 - current
Director of Department of Molecular Immunology and Associate Member, John Wayne Cancer Institute	1991 - 1997
Assistant Professor, Department of Surgery, UCLA School of Medicine	1987 - 1991

Professional Affiliations

- Member of American Association of Cancer Research
- Member of American Association of Clinical Oncology

Publications

I have about 190 publications either by myself or with others in the field of oncology and immunology.

4. I have read and understood the specification of the application and the Office Action dated September 15, 2006. I am making this declaration in support of my view that a non-sentinel lymph node (NSLN) sample can be used in a method for melanoma prognosis, the method comprising:

(a) isolating nucleic acid from a non-sentinel lymph node (NSLN) sample obtained from a melanoma patient;

(b) amplifying nucleic acid targets from a panel of marker genes, wherein the panel comprises GalNAcT, PAX3, or both;

(c) detecting the levels of the nucleic acid targets; and

(d) predicting melanoma recurrence, disease-free survival, overall survival, or a combination thereof, based on the levels of the nucleic acid targets, wherein, as compared to control levels, an increase in the levels of the nucleic acid targets is indicative of an increase in melanoma recurrence, a decrease in disease-free survival, or a decrease in overall survival, and a decrease in the levels of the nucleic acid targets is indicative of a decrease in melanoma recurrence, an increase in disease-free survival, or an increase in overall survival.

5. In support of my opinion that an NSLN sample can be used for melanoma prognosis as described in Paragraph 4, I provide the following information:

Molecular Upstaging by qRT of Non-SLN (NSLN) in Melanoma Patients

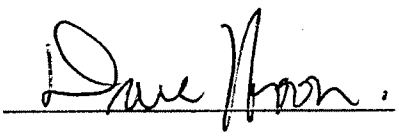
NSLNs of melanoma patients who had histopathology negative and positive SLN were evaluated. 22 patients were assessed for occult tumor cells by multimarker qRT. These patients were PE (paraffin-embedded) SLN histopathology (-) and matched PE NSLN from the original SLN/CLND (complete lymph node dissection) verification study. The NSLN for individual patients ranged from 8-40 nodes (> 250 nodes). All NSLN specimens were coded and run in a blinded fashion. These NSLN specimens were up to 17 years. Some RNA degradation may have occurred in specimens older than 10 years.

Multimarker qRT was performed. mRNA markers Mart-1, Trp-2, GalNAcT, Pax-3, and Mage-3 were assessed depending on the quality and amount of RNA retrieved. Respective controls (house-keeping genes) were assessed. 11 of the 22 (50%) patients were upstaged by multimarker qRT of the NSLN: 8 (73%) patients had qRT (+) SLNs and NSLNs and 3 (14%) patients had qRT (+) NSLN but qRT (-) SLN. Of the 11 patients whose disease recurred during long-term follow-up, 8 patients (73%) had been molecularly upstaged.

6. On the basis of the information summarized in Paragraph 5, I am of the view that an NSLN sample can be used for melanoma prognosis as described in Paragraph 4.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that a willful false statement and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATE: December 15, 2006

By: 

Dave S.B. Hoon, Ph.D.